Case 2:19-cv-04959-NIQA Document 1 Filed 10/23/19 Page 1 of 27

JS 44 (Rev. 02/19)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

purpose of initiating the civil of	ocket sheet. (SEE INSTRUC	CHONS ON NEXT TAGE C	n marc	/IUI.)			
I. (a) PLAINTIFFS			DEFENDANTS				
ANDY VELAYOS, Individually and On Behalf of All				ZYNERBA PHARMACEUTICALS, INC., ARMANDO			
Others Similarly Situated,				ANIDO, and JAMES E. FICKENSCHER,			
()	of First Listed Plaintiff	Tarrant County, To	exas	County of Residence	of First Listed Defendant		
(E	XCEPT IN U.S. PLAINTIFF C	ASES)			(IN U.S. PLAINTIFF CASES (
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(c) Attorneys (Firm Name,		er)		Attorneys (If Known)			
The Rosen Law I		ulaintana DA 100/	1.6	ŀ			
Telephone: (215)	Avenue, Suite 440, Jen	nkintowii, PA 1902	+0				
II. BASIS OF JURISD		One Roy Only	III CI	TIZENSHIP OF P	RINCIPAL PARTIES	(Place an "X" in One Box for Plaintiff	
		The Box Only)		(For Diversity Cases Only)		and One Box for Defendant)	
☐ 1 U.S. Government Plaintiff	(U.S. Government Not a Party)		Citia		TF DEF □ 1 □ 1 Incorporated or Pr	PTF DEF	
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☐ 2 U.S. Government	☐ 4 Diversity		Citize	en of Another State	2	Principal Place 5 5 5	
Defendant		nip of Parties in Item III)	Citiza	on of Another State	of Business In		
			Citize	en or Subject of a	3 🗇 3 Foreign Nation	□ 6 □ 6	
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IV. NATURE OF SUIT						of Suit Code Descriptions.	
CONTRACT		ORTS		ORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
☐ 110 Insurance ☐ 120 Marine	PERSONAL INJURY ☐ 310 Airplane	PERSONAL INJUR 365 Personal Injury -	Y 62	5 Drug Related Seizure of Property 21 USC 881	☐ 422 Appeal 28 USC 158 ☐ 423 Withdrawal	☐ 375 False Claims Act☐ 376 Qui Tam (31 USC	
☐ 130 Miller Act	315 Airplane Product	Product Liability	1 69	0 Other	28 USC 157	3729(a))	
☐ 140 Negotiable Instrument☐ 150 Recovery of Overpayment☐	Liability ☐ 320 Assault, Libel &	☐ 367 Health Care/ Pharmaceutical			PROPERTY RIGHTS	☐ 400 State Reapportionment ☐ 410 Antitrust	
& Enforcement of Judgment	Slander	Personal Injury			☐ 820 Copyrights	 430 Banks and Banking 	
☐ 151 Medicare Act ☐ 152 Recovery of Defaulted	☐ 330 Federal Employers' Liability	Product Liability 368 Asbestos Personal	.		☐ 830 Patent ☐ 835 Patent - Abbreviated	☐ 450 Commerce ☐ 460 Deportation	
Student Loans	☐ 340 Marine	Injury Product	·		New Drug Application	470 Racketeer Influenced and	
(Excludes Veterans) ☐ 153 Recovery of Overpayment	☐ 345 Marine Product Liability	Liability PERSONAL PROPER	OTV	LABOR	■ 840 Trademark SOCIAL SECURITY	Corrupt Organizations 480 Consumer Credit	
of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 370 Other Fraud		0 Fair Labor Standards	□ 861 HIA (1395ff)	485 Telephone Consumer	
☐ 160 Stockholders' Suits ☐ 190 Other Contract	☐ 355 Motor Vehicle	☐ 371 Truth in Lending ☐ 380 Other Personal	72	Act 0 Labor/Management	☐ 862 Black Lung (923) ☐ 863 DIWC/DIWW (405(g))	Protection Act 490 Cable/Sat TV	
☐ 195 Contract Product Liability	Product Liability 360 Other Personal	Property Damage		Relations	☐ 864 SSID Title XVI	850 Securities/Commodities/	
☐ 196 Franchise	Injury 362 Personal Injury -	☐ 385 Property Damage Product Liability		0 Railway Labor Act 1 Family and Medical	□ 865 RSI (405(g))	Exchange 890 Other Statutory Actions	
	Medical Malpractice			Leave Act		☐ 891 Agricultural Acts	
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITION		0 Other Labor Litigation	FEDERAL TAX SUITS	□ 893 Environmental Matters □ 895 Freedom of Information	
210 Land Condemnation220 Foreclosure	☐ 440 Other Civil Rights ☐ 441 Voting	Habeas Corpus: ☐ 463 Alien Detainee	10 /9	1 Employee Retirement Income Security Act	☐ 870 Taxes (U.S. Plaintiff or Defendant)	Act	
230 Rent Lease & Ejectment	☐ 442 Employment	☐ 510 Motions to Vacate	,	•	☐ 871 IRS—Third Party	□ 896 Arbitration	
240 Torts to Land245 Tort Product Liability	☐ 443 Housing/ Accommodations	Sentence 530 General			26 USC 7609	☐ 899 Administrative Procedure Act/Review or Appeal of	
☐ 290 All Other Real Property	☐ 445 Amer. w/Disabilities -	☐ 535 Death Penalty		IMMIGRATION		Agency Decision	
	Employment 446 Amer. w/Disabilities -	Other: 540 Mandamus & Oth		2 Naturalization Application 5 Other Immigration		☐ 950 Constitutionality of State Statutes	
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	☐ 448 Education	☐ 555 Prison Condition☐ 560 Civil Detainee -					
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	Sections 10(h):	atute under which you are and 20(a) of the Ex-	re filing (D change /	o not cite jurisdictional stat Act	utes unless diversity):		
VI. CAUSE OF ACTION	Brief description of ca	ause:					
	Defendants alle	gedly engaged in ac		in violation of Feder			
VII. REQUESTED IN	CHECK IF THIS	IS A CLASS ACTION) DI	EMAND \$	•	if demanded in complaint:	
COMPLAINT:	UNDER RULE 2	.5, F.R.CV.P.			JURY DEMAND:	X Yes No	
VIII. RELATED CASI	(See instructions).						
IF ANY	10 V 1111	/JUDGE			DOCKET NUMBER		
DATE	(X) , (1) (V)	SIGNATURE OF AT	TORNEY O	F RECORD			
10/23/2019 FOR OFFICE USE ONLY	NUVIV				<u>.</u>		
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Case 2:19-cv-04959-NIQA Document 1 Filed 10/23/19 Page 2 of 27 UNITED STATES DISTRICT COURT

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: 4208 Inwood Road, Fort Worth, Texas 76109					
Address of Defendant: 80 W. Lancaster Avenue, Suite 300, Devon, PA 19333					
Place of Accident, Incident or Transaction: Pennsylvania					
RELATED CASE, IF ANY:					
Case Number:					
Civil cases are deemed related when Yes is answered to any of the following questions:					
1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?					
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court?					
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court?					
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights Yes No X					
I certify that, to my knowledge, the within case is / is not this court except as noted above.					
DATE: 10/23/2019 Attorney-at-Law / Pro Se Plaintiff Attorney I.D. # (if applicable)					
CIVIL: (Place a √ in one category only)					
A. Federal Question Cases: B. Diversity Jurisdiction Cases: 1. Indemnity Contract, Marine Contract, and All Other Contracts 2. FELA 1. Insurance Contract and Other Contracts 2. Airplane Personal Injury					
□ 3. Jones Act-Personal Injury □ 3. Assault, Defamation □ 4. Antitrust □ 4. Marine Personal Injury □ 5. Patent □ 5. Motor Vehicle Personal Injury □ 6. Labor-Management Relations □ 6. Other Personal Injury (Please specify) □ 7. Civil Rights □ 7. Products Liability					
8. Habeas Corpus 9. Securities Act(s) Cases 10. Social Security Review Cases 11. All other Federal Question Cases (Please specify)					
ARBITRATION CERTIFICATION (The effect of this certification is to remove the case from eligibility for arbitration.)					
I, <u>Jacob A. Goldberg</u> , counsel of record <i>or</i> pro se plaintiff, do hereby certify:					
Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs					
X Relief other than monetary damages is sought.					
DATE: 10/23/2019 Attorney-at-Law / Pro Se Plaintiff Attorney I.D. # (if applicable)					
NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.					

Case 2:19-cv-04959-NIQA Document 1 Filed 10/23/19 Page 3 of 27 UNITED STATES DISTRICT COURT

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: 4208 Inwood Road, Fort Worth, Texas 76109				
Address of Defendant: 80 W. Lancaster Avenue, Suite 300, Devon, PA 19333				
Place of Accident, Incident or Transaction: Pennsylvania				
RELATED CASE, IF ANY:				
Case Number: Judge: Date Terminated:				
Civil cases are deemed related when Yes is answered to any of the following questions:				
1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court?				
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit yes No X pending or within one year previously terminated action in this court?				
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court?				
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights Yes No X				
I certify that, to my knowledge, the within case is / is not trelated to any case now pending or within one year previously terminated action in this court except as noted above.				
DATE: 10/23/2019 Attorney-at-Law / Pro Se Plaintiff Attorney I.D. # (if applicable)				
CIVIL: (Place a √ in one category only)				
A. Federal Question Cases: B. Diversity Jurisdiction Cases:				
□ 1. Indemnity Contract, Marine Contract, and All Other Contracts □ 1. Insurance Contract and Other Contracts □ 2. FELA □ 2. Airplane Personal Injury				
 □ 3. Jones Act-Personal Injury □ 4. Antitrust □ 3. Assault, Defamation □ 4. Marine Personal Injury 				
□ 5. Patent □ 5. Motor Vehicle Personal Injury □ 6. Labor-Management Relations □ 6. Other Personal Injury (Please specify)				
7. Civil Rights 7. Products Liability				
□ 8. Habeas Corpus □ 8. Products Liability – Asbestos □ 9. Securities Act(s) Cases □ 9. All other Diversity Cases				
☐ 10. Social Security Review Cases (Please specify)				
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ARBITRATION CERTIFICATION (The effect of this certification is to remove the case from eligibility for arbitration.)				
(The effect of this certification is to remove the case from eligibility for arbitration.)				
(The effect of this certification is to remove the case from eligibility for arbitration.) I, Jacob A. Goldberg , counsel of record or pro se plaintiff, do hereby certify: Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case				
(The effect of this certification is to remove the case from eligibility for arbitration.) I, Jacob A. Goldberg				

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

CIVIL ACTION

ANDY VELAYOS, Individually and On Behalf of All :

Others Similarly Situated,	:	CIVIL ACTION		
V. ZYNERBA PHARMACEUTICA ARMANDO ANIDO, and JAMI		NO.		
plaintiff shall complete a Ca filing the complaint and serve side of this form.) In the edesignation, that defendant s	se Management Track Dese a copy on all defendants. event that a defendant does thall, with its first appearanties, a Case Management	lay Reduction Plan of this court, counsignation Form in all civil cases at the to (See § 1:03 of the plan set forth on the reserved not agree with the plaintiff regarding note, submit to the clerk of court and set Track Designation Form specifying the signed.	ime of everse g said rve on	
SELECT ONE OF THE FO	OLLOWING CASE MAI	NAGEMENT TRACKS:		
(a) Habeas Corpus – Cases I	orought under 28 U.S.C. §	2241 through § 2255.	()	
(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits.				
(c) Arbitration – Cases requ	ired to be designated for a	rbitration under Local Civil Rule 53.2.	()	
(d) Asbestos – Cases involve exposure to asbestos.	ing claims for personal inj	ury or property damage from	()	
commonly referred to as	complex and that need sp	racks (a) through (d) that are ecial or intense management by iled explanation of special	(X)	
(f) Standard Management –	Cases that do not fall into	/	()	
<u>10/23/2019</u> Date	Attorney-at-law	Plaintiff Attorney for		
215-600-2817	212-202-3827	jgoldberg@rosenlegal.co	m	
Telephone	FAX Number	E-Mail Address		

(Civ. 660) 10/02

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

ANDY VELAYOS, Individually and On Behalf of All Others Similarly Situated,)) Case No.
Plaintiff,))
V	CLASS ACTION COMPLAINT
ZYNERBA PHARMACEUTICALS, INC., ARMANDO ANIDO, and JAMES E. FICKENSCHER,)) <u>JURY TRIAL DEMANDED</u>)))
Defendants	

Plaintiff Andy Velayos ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Zynerba Pharmaceuticals, Inc. ("Zynerba" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

- 1. This is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased or otherwise acquired Zynerba securities between March 11, 2019 and September 17, 2019, both dates inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.
- 2. Zynerba was founded in 2007 and is headquartered in Devon, Pennsylvania. The Company was formerly known as AllTranz, Inc. and changed its name to Zynerba Pharmaceuticals, Inc. in August 2014. Zynerba operates as a clinical stage specialty pharmaceutical company. It focuses on developing pharmaceutically-produced transdermal cannabinoid ("CBD") therapies for rare and near-rare neuropsychiatric disorders.
- 3. Zynerba is developing, among other product candidates, Zygel (ZYN002), a transdermal CBD gel, which is in a Phase II clinical trial for treating children and adolescent patients with developmental and epileptic encephalopathies ("DEE"); a Phase II/III clinical trial to treat children and adolescent patients with fragile X syndrome; and a Phase II clinical trial for treating children and adolescent patients with autism spectrum disorder. In April 2018, Zynerba initiated the Phase 2 BELIEVE 1 (Open Label Study to Assess the Safety and Efficacy of Zygel Administered as a Transdermal Gel to Children and Adolescents with Developmental and Epileptic Encephalopathy) clinical trial ("BELIEVE 1 Trial"), a six-month open label multi-dose clinical trial designed to evaluate the efficacy and safety of Zygel in children and adolescents (ages three to seventeen years) with DEE as classified by the International League Against Epilepsy ("ILAE").

- 4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Zygel was proving unsafe and not well-tolerated in the BELIEVE 1 Trial; (ii) the foregoing created a foreseeable, heightened risk that Zynerba would fail to secure the necessary regulatory approvals for commercializing Zygel for the treatment of DEE in children and adolescents; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.
- 5. On September 18, 2019, during pre-market hours, Zynerba issued a press release announcing results from the BELIEVE 1 Trial evaluating topical gel Zygel in children and adolescents with DEE (the "September 2019 Press Release"). While Zynerba asserted that Zygel was well-tolerated in the September 2019 Press Release, it also disclosed that, among patients enrolled in the BELIEVE 1 Trial, the rate of treatment emergent adverse events ("TEAEs") was 96%, the rate of treatment related adverse events ("TRAEs") was 60%, and there were ten patients who reported serious adverse events ("SAEs"), of which, "two SAEs (lower respiratory tract infection and status epilepticus) were determined to be possibly related to treatment." Specifically, the September 2019 Press Release stated, in relevant part:

Zygel was well tolerated, and the safety profile was consistent with previously released data from Zygel clinical trials. Eight patients discontinued the study; one discontinued as a result of an application site reaction, and seven discontinued as a result of withdrawal of consent or perceived lack of efficacy. Through six months of therapy, ninety-six percent (96%) of patients experienced a treatment emergent adverse event (TEAE) and 60% of patients experienced a treatment related adverse event. Most were mild to moderate. The most common treatment related adverse events (in >5% of patients) are application site dryness (8.3%), application site pain (8.3%), and somnolence (8.3%). Ten patients reported a serious adverse event (SAE); most were infection-related. Two SAEs (lower respiratory tract infection and status epilepticus) were determined to be possibly related to treatment. There were no patient deaths during the study.

(Emphases added.)

- 6. On this news, Zynerba's stock price fell \$2.46 per share, or 21.77%, to close at \$8.84 per share on September 18, 2019.
- 7. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

- 8. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).
- 9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.
- 10. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Zynerba is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' activities took place within this Judicial District.
- 11. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

12. Plaintiff, as set forth in the attached Certification, acquired Zynerba securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

- 13. Zynerba is a Delaware corporation with principal executive offices located at 80 W. Lancaster Avenue, Suite 300, Devon, PA 19333. The Company's stock trades in an efficient market on the NASDAQ Global Market ("NASDAQ") under the ticker symbol "ZYNE."
- 14. Defendant Armando Anido ("Anido") has served as Zynerba's Chairman and Chief Executive Officer at all relevant times.
- 15. Defendant James E. Fickenscher ("Fickenscher") has served as Zynerba's Chief Financial Officer at all relevant times.
- 16. Defendants Anido and Fickenscher are sometimes referred to herein as the "Individual Defendants."
- 17. The Individual Defendants possessed the power and authority to control the contents of Zynerba's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Zynerba's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Zynerba, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

18. Zynerba was founded in 2007 and is headquartered in Devon, Pennsylvania. The Company was formerly known as AllTranz, Inc. and changed its name to Zynerba

Pharmaceuticals, Inc. in August 2014. Zynerba operates as a clinical stage specialty pharmaceutical company. The Company focuses on developing pharmaceutically-produced transdermal CBD therapies for rare and near-rare neuropsychiatric disorders.

- 19. Zynerba is developing, among other product candidates, Zygel (ZYN002), a transdermal CBD gel, which is in a Phase II clinical trial for treating children and adolescent patients with DEE; a Phase II/III clinical trial to treat children and adolescent patients with fragile X syndrome; and a Phase II clinical trial for treating children and adolescent patients with autism spectrum disorder.
- 20. In April 2018, Zynerba initiated the BELIEVE 1 Trial, a six-month open label multi-dose clinical trial designed to evaluate the efficacy and safety of Zygel in children and adolescents (ages three to seventeen years) with DEE as classified by the ILAE. Enrollment in this study was completed in December 2018 and forty-eight patients with confirmed DEE were dosed in the clinical trial, 27% of whom had either Dravet or Lennox-Gastaut syndrome. Enrolled patients would receive weight-based initial doses of 250 mg daily or 500 mg daily and during the maintenance phase patients could receive up to 1000 mg daily of Zygel. The primary endpoint was change in seizure frequency from baseline.

Materially False and Misleading Statements Issued During the Class Period

21. The Class Period begins on March 11, 2019, when Zynerba filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2018 (the "2018 10-K"). While Zynerba would later reveal that, among patients enrolled in the BELIEVE 1 Trial, there was a near-universal (96%) rate of TEAEs, a 60% rate of TRAEs, and ten patients reported SAEs (at least two of which were determined to be possibly related to treatment), the 2018 10-K—which was filed months after

enrollment in the BELIEVE 1 Trial was already completed and, presumably, dosing was already underway and being observed—reported no adverse events in patients, and provided no information on Zygel's safety profile as observed in that study. Rather, with respect to the BELIEVE 1 Trial, the 2018 10-K merely stated, in relevant part:

In April 2018, we initiated the Phase 2 BELIEVE 1 (Open Label Study to Assess the Safety and Efficacy of Zygel Administered as a Transdermal Gel to Children and Adolescents with Developmental and Epileptic Encephalopathy) clinical trial, a six-month open label multi-dose clinical trial designed to evaluate the efficacy and safety of Zygel in children and adolescents (three to 17 years) with DEE as classified by the International League Against Epilepsy (ILAE) (Scheffer et al. 2017). Enrollment in this study was complete in December 2018 and 48 patients with confirmed DEE are being dosed in the clinical trial, 27% of whom have either Dravet or Lennox-Gastaut syndrome. Enrolled patients will receive weight-based initial doses of 250 mg daily or 500 mg daily and during the maintenance phase patients may receive up to 1000 mg daily of Zygel. The primary endpoint is change in seizure frequency from baseline. We expect to report top line results from the BELIEVE 1 trial in the third quarter of 2019.

22. Additionally, the 2018 10-K touted the purported benefits of CBD for treating patients suffering from DEE, stating, in relevant part:

We believe that Zygel may provide an effective treatment for epilepsy based on the anticonvulsant effects of CBD due to its ability to reduce neuronal hyperexcitability shown in multiple *in vivo* models of epilepsy and clinical trials conducted by third parties. Epilepsy specialists and patient organizations have shown considerable interest in the potential therapeutic role of CBD in adults with epilepsy and especially, children with DEE.

- 23. The 2018 10-K also contained a series of merely generic, boilerplate representations concerning Zynerba's risks related to poor clinical results, including, but not limited to, the following:
 - "Because the results of preclinical studies and earlier clinical trials are not necessarily predictive of future results, Zygel may not have favorable results in our planned clinical trials."
 - "Failures or delays in our clinical trials of Zygel could result in increased costs to us and could delay, prevent or limit our ability to generate revenue and continue our business."

• "The regulatory approval processes of the FDA, the EMA and other comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed."

(All emphases in original.) Plainly, the foregoing risk warnings were generic "catch-all" provisions that were not tailored to Zynerba's actual known risks related to adverse events reported in the BELIEVE 1 Trial.

- 24. Appended as exhibits to the 2018 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein the Individual Defendants certified that "[t]he [2018 10-K] fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934," and that "[t]he information contained in the [2018 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."
- 25. On May 8, 2019, Zynerba filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2019 (the "1Q19 10-Q"). As with the 2018 10-K, even though Zynerba would ultimately reveal that, among patients enrolled in the BELIEVE 1 Trial, there was a near-universal (96%) rate of TEAEs, a 60% rate of TRAEs, and ten patients reported SAEs (at least two of which were determined to be possibly related to treatment), the 1Q19 10-Q—filed months after enrollment in the BELIEVE 1 Trial was already completed—reported no adverse events in patients, and provided no information on Zygel's safety profile as observed in that study. Rather, with respect to the BELIEVE 1 Trial, the 1Q19 10-Q merely reiterated substantively the same statements as contained in the 2018 10-K, as quoted above at ¶ 21, with the only difference being that the 1Q19 10-Q confirmed dosing was already underway, stating, in relevant part: "Patients *received* weight-based initial doses of

250 mg or 500 mg daily and during the maintenance phase patients *receive* up to 1000 mg daily of Zygel." (Emphasis added.)

- 26. With respect to risk factors related to poor clinical results, the 1Q19 10-Q referenced the same risk factors contained in the 2018 10-K, which included the same merely generic, boilerplate representations quoted above at ¶ 23, stating: "You should carefully consider the risk factors described in our December 31, 2018 Annual Report, under the caption 'Item 1A. 'Risk Factors'. There have been no material changes to the risk factors disclosed in our 2018 Annual Report."
- 27. Appended as exhibits to the 1Q19 10-Q were signed SOX certifications, wherein the Individual Defendants certified that "[t]he [1Q19 10-Q] fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934," and that "[t]he information contained in the [1Q19 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."
- 28. On June 7, 2019, roughly three months before the truth was revealed regarding safety signals in the BELIEVE 1 Trial, Zynerba released a slideshow presentation for investors discussing, among other product pipelines, Zygel in the BELIEVE 1 Trial for treating patients with DEE. In the slideshow, Defendants cited a "[c]ompelling rationale for [the] utility of CBD in DEE" based on "[t]hird party clinical data show[ing] [the] impact of CBD on seizures and behavioral issues in children[.]" With respect to the BELIEVE 1 Trial, the slideshow merely stated, in relevant part:
 - Patient enrollment in BELIEVE 1 Phase 2 study complete
 - Six month multi-dose study in DEE patients (3 through 17 years)
 - Being Conducted in Australia and New Zealand
 - Inclusion criteria require ≥5 generalized motor seizures during baseline
 - ~27% have Dravet or LGS [Lennox-Gastaut syndrome]
 - Primary efficacy assessment: change in seizure frequency

- Top line results expected in 3Q2019
- 29. On August 6, 2019, Zynerba filed a Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2019 (the "2Q19 10-Q"). As with the 2018 10-K and 1Q19 10-Q, even though Zynerba would ultimately reveal that, among patients enrolled in the BELIEVE 1 Trial, there was a near-universal (96%) rate of TEAEs, a 60% rate of TRAEs, and ten patients reported SAEs (at least two of which were determined to be possibly related to treatment), the 2Q19 10-Q—filed months after enrollment in the BELIEVE 1 Trial was already completed and, according to the 1Q19 10-Q, dosing was already underway and presumably being observed—reported no adverse events in patients, and provided no information on Zygel's safety profile as observed in that study. Rather, with respect to the BELIEVE 1 Trial, and like the 1Q19 10-Q, the 2Q19 10-Q merely reiterated substantively the same statements as those contained in the 2018 10-K, as quoted above in ¶ 21, and reiterated that dosing was already underway.
- 30. With respect to risk factors related to poor clinical results, the 2Q19 10-Q referenced the same risk factors contained in the 2018 10-K, which included the same merely generic, boilerplate representations quoted above in ¶ 23, stating: "You should carefully consider the risk factors described in our December 31, 2018 Annual Report, under the caption 'Item 1A. 'Risk Factors.' There have been no material changes to the risk factors disclosed in our 2018 Annual Report."
- 31. Appended as exhibits to the 2Q19 10-Q were signed SOX certifications, wherein the Individual Defendants certified that "[t]he [2Q19 10-Q] fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934," and that "[t]he information

contained in the [2Q19 10-Q] fairly presents, in all material respects, the financial condition and results of operations of the Company."

- 32. Then, on August 12, 2019, the month before the truth was revealed regarding safety signals in the BELIEVE 1 Trial, Zynerba released yet another slideshow presentation for investors that, instead of disclosing a negative trend of adverse events among the study's patient population, merely reiterated the statements quoted in ¶ 28 above, which were released in the slideshow presentation for investors on June 7, 2019.
- 33. The statements referenced in ¶¶21-32 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operational and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) Zygel was proving unsafe and not well-tolerated in the BELIEVE 1 Trial; (ii) the foregoing created a foreseeable, heightened risk that Zynerba would fail to secure the necessary regulatory approvals for commercializing Zygel for the treatment of DEE in children and adolescents; and (iii) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Begins to Emerge

34. On September 18, 2019, during pre-market hours, Zynerba issued a press release announcing results from the BELIEVE 1 Trial evaluating topical gel Zygel in children and adolescents with DEE. While Zynerba asserted that Zygel was well-tolerated in the September 2019 Press Release, it also disclosed that, among patients enrolled in the BELIEVE 1 Trial, the rate of TEAEs was 96%, the rate of TRAEs was 60%, and there were ten patients who reported SAEs, of which, "two SAEs (lower respiratory tract infection and status epilepticus) were

determined to be possibly related to treatment." Specifically, the September 2019 Press Release stated, in relevant part:

Zygel was well tolerated, and the safety profile was consistent with previously released data from Zygel clinical trials. Eight patients discontinued the study; one discontinued as a result of an application site reaction, and seven discontinued as a result of withdrawal of consent or perceived lack of efficacy. Through six months of therapy, ninety-six percent (96%) of patients experienced a treatment emergent adverse event (TEAE) and 60% of patients experienced a treatment related adverse event. Most were mild to moderate. The most common treatment related adverse events (in >5% of patients) are application site dryness (8.3%), application site pain (8.3%), and somnolence (8.3%). Ten patients reported a serious adverse event (SAE); most were infection-related. Two SAEs (lower respiratory tract infection and status epilepticus) were determined to be possibly related to treatment. There were no patient deaths during the study.

(Emphases added.)

- 35. On this news, Zynerba's stock price fell \$2.46 per share, or 21.77%, to close at \$8.84 per share on September 18, 2019.
- 36. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

37. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Zynerba securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

- 38. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Zynerba securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Zynerba or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.
- 39. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.
- 40. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.
- 41. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:
 - whether the federal securities laws were violated by Defendants' acts as alleged herein;
 - whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Zynerba;
 - whether the Individual Defendants caused Zynerba to issue false and misleading financial statements during the Class Period;
 - whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of Zynerba securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.
- 42. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.
- 43. Plaintiff will rely, in part, upon the presumption of reliance established by the fraudon-the-market doctrine in that:
 - Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
 - the omissions and misrepresentations were material;
 - Zynerba securities are traded in an efficient market;
 - the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;
 - the Company traded on the NASDAQ and was covered by multiple analysts;
 - the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
 - Plaintiff and members of the Class purchased, acquired and/or sold Zynerba securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.
- 44. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

45. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

- 46. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.
- 47. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.
- A8. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Zynerba securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Zynerba securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

- 49. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Zynerba securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Zynerba's finances and business prospects.
- 50. By virtue of their positions at Zynerba, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.
- 51. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of Zynerba, the Individual Defendants had knowledge of the details of Zynerba's internal affairs.
- 52. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of

Zynerba. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Zynerba's businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Zynerba securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Zynerba's business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Zynerba securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

During the Class Period, Zynerba securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Zynerba securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of Zynerba securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Zynerba securities declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

- 54. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.
- 55. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

- 56. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.
- 57. During the Class Period, the Individual Defendants participated in the operation and management of Zynerba, and conducted and participated, directly and indirectly, in the conduct of Zynerba's business affairs. Because of their senior positions, they knew the adverse non-public information about Zynerba's misstatement of income and expenses and false financial statements.
- 58. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Zynerba's financial condition and results of operations, and to correct promptly any public statements issued by Zynerba which had become materially false or misleading.
- 59. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and

public filings which Zynerba disseminated in the marketplace during the Class Period concerning Zynerba's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Zynerba to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Zynerba within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Zynerba securities.

- 60. Each of the Individual Defendants, therefore, acted as a controlling person of Zynerba. By reason of their senior management positions and/or being directors of Zynerba, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Zynerba to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Zynerba and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.
- 61. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Zynerba.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

- A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
- B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
- C. Awarding Plaintiff and the other members of the Class prejudgment and postjudgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: October 23, 2019

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

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Attorneys for Plaintiff

CERTIFICATION PURSUANT TO FEDERAL SECURITIES LAWS

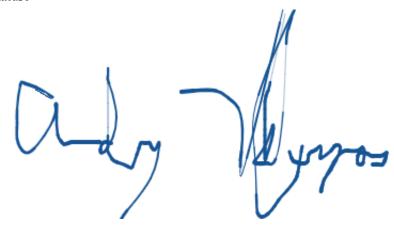
- 1. I make this declaration pursuant to Section 27(a)(2) of the Securities Act of 1933 ("Securities Act") and/or Section 21D(a)(2) of the Securities Exchange Act of 1934 ("Exchange Act") as amended by the Private Securities Litigation Reform Act of 1995.
- 2. I have reviewed a Complaint against Zynerba Pharmaceuticals, Inc. ("Zynerba" or the "Company") and authorize the filing of a comparable complaint on my behalf.
- 3. I did not purchase or acquire Zynerba securities at the direction of plaintiffs' counsel or in order to participate in any private action arising under the Securities Act or Exchange Act.
- 4. I am willing to serve as a representative party on behalf of a Class of investors who purchased or acquired Zynerba securities during the class period, including providing testimony at deposition and trial, if necessary. I understand that the Court has the authority to select the most adequate lead plaintiff in this action.
- 5. To the best of my current knowledge, the attached sheet lists all of my transactions in Zynerba securities during the Class Period as specified in the Complaint.
- 6. During the three-year period preceding the date on which this Certification is signed, I have not sought to serve as a representative party on behalf of a class under the federal securities laws.
- 7. I agree not to accept any payment for serving as a representative party on behalf of the class as set forth in the Complaint, beyond my pro rata share of any recovery, except such reasonable costs and expenses directly relating to the representation of the class as ordered or approved by the Court.
- 8. I declare under penalty of perjury that the foregoing is true and correct.

Name

Print Name

Andy Velayos

Signature



Zynerba Pharmaceuticals, Inc. (ZYNE)

Velayos, Andy

List of Purchases and Sales

Purchase		Number of	Price Per	
Date	or Sale	Shares/Unit	Share/Unit	
4/8/2019	Purchase	4,600	\$9.1000	
5/20/2019	Purchase	1,600	\$14.8097	
5/28/2019	Purchase	300	\$12.2293	
7/18/2019	Purchase	375	\$11.9147	
8/2/2019	Purchase	350	\$9.8000	
4/8/2019	Sale	(4,600)	\$8.5100	
9/12/2019	Sale	(300)	\$12.3500	